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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,081	12/02/2003	Jon Elliot Adler	54072D4	2720

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,081	ADLER ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *287-338* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *287-338* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1) Claims 287 to 338 are pending in the instant application. Claims 235 to 286 have been canceled and claims 287 to 338 have been added as requested by Applicant in the correspondence filed 19 November of 2007.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4) Claims 287 and 296 to 338 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass a binding assay that can employ a nucleic acid encoding a "T1R3" protein wherein that protein is structurally defined solely by the implied limitation of being encoded by "a nucleic acid sequence that hybridizes to the T1R3 polypeptide coding region of the nucleic acid sequence contained in SEQ. ID. NO: 2, SEQ ID NO:3 or SEQ. ID. NO: 20 under stringent hybridization conditions". Given that a single change in a nucleotide sequence can add a stop codon or cause a frame shift anywhere within a coding sequence within that nucleotide sequence, these claims encompass a process that employs a polypeptide having little or no sequence identity to SEQ ID NO:4 of the instant

application. However, the instant specification does not provide the guidance needed to practice the claimed process with a "human T1R3" polypeptide comprising anything less than 90% of the entire amino acid sequence presented in SEQ ID NO:4. The only manner described in the instant specification of using the claimed method is in the identification of compounds that have potential use because of their ability to agonize or antagonize the human taste receptor protein described therein. The claimed invention is only useful in so far as the "T1R3" protein employed in the claimed assay responds in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

One of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments encoded by a nucleic acid sequence that hybridizes to the T1R3 polypeptide coding region of the nucleic acid sequence contained in SEQ. ID. NO: 2, SEQ ID NO:3 or SEQ. ID. NO: 20 under stringent

hybridization conditions, or fragments thereof, are going to be functional, much less be capable of producing an authentic response. Because the instant specification does not identify those amino acid residues in SEQ ID NO:4 which are critical to the structural and functional integrity of a "T1R3" receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified "T1R3" protein of the instant invention, an artisan can not practice the invention commensurate with the scope of these claims.

Applicant is advised that a process which employs a "human T1R3" which is encoded by a nucleic acid sequence that hybridizes to the complement of the T1R3 polypeptide coding region of the nucleic acid sequence contained in SEQ. ID. NO: 2, SEQ ID NO:3 or SEQ. ID. NO: 20 under stringent hybridization conditions" is enabled by the instant specification since it would be limited to naturally occurring proteins. Applicant is further advised that the specification is enabled for a process that employs "T1R3 polypeptide that comprises an amino acid sequent that is at least 95% identical to the amino acid sequence of SEQ ID NO:4" wherein that polypeptide is not necessarily "human". It is noted that a T1R3 polypeptide of the instant invention is a member of the G protein-coupled receptor (GPCR) family. Because there was a substantial amount of information available with respect to the structural and functional features of GPCRs at the time of the instant invention, one of ordinary skill could reasonably predict the effects of minor modifications to specific portions of the sequence of almost any GPCR at that time.

5) Claim 302 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim is drawn to a method for identifying a compound that putatively elicits or modulates taste in a human subject based on its effect on the activation of a taste receptor comprising a human T1R3 polypeptide wherein that polypeptide is expressed in a prokaryotic cell. This claim is not enabled because there is absolutely no evidence that mammalian taste receptor can be functionally expressed in even a single species of bacteria, much less any and all prokaryotes. There is neither a reference of record nor a single working example provided by the instant application of the expression of a fully functional G protein-coupled receptor in a bacterial host cell. This claim essentially encompasses a process that has never been successfully executed with any sensory receptor, much less a taste receptor.

Further, there is no evidence of record that any species of bacterium has ever been discovered which inherently produces a member of the G protein-coupled receptor family. Given the complex structure of a receptor protein of the instant invention and the complex and varied structural features of the cell wall/membrane systems found in bacteria one has no reasonable expectation that a mammalian taste receptor could be expressed in a prokaryotic cell in such a way that it retains the ability to functionally interact with any of the signal transduction pathway components required to detect the activation of that receptor by a ligand. A patent is granted for a completed invention, not

the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method in a bacterial host without first making a substantial inventive contribution, if at all.

6) Claims 288 to 295 and 297 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 289 to 295 and 297 are vague and indefinite because there is no antecedent basis for "the polypeptide in SEQ ID NO:4". As indicated by claim 288, SEQ ID NO:4 is an amino acid sequence, not a polypeptide. Contrary to the suggestion made in the previous office action, claims 288 to 295 and 297 should refer to "the amino acid sequence **of** SEQ ID NO:4". They are potentially confusing in their present form because it is unclear if the limitation "in SEQ ID NO:4" requires the entire amino acid sequence presented therein or only a portion thereof.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7) Claims 287 to 299, 301, 303, 304, 308 to 312, 315, 316, 318, 320, 321, 325, 326, 328 and 332 to 338 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims encompass the act of tasting food by a human being, which is not new nor is it the invention of Applicant. The express limitations recited in these claims are inherent to that process. For example, the perception of a sweet taste in a food inherently "detects the effect of said compound on the dissociation of said T1R3 polypeptide and a G protein" as required by claim 309 because that process is an inherent step in the signal transduction pathway of taste perception.

Response to Arguments

8) Applicant's arguments filed 19 November of 2007 have been fully considered but they are not persuasive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John D. Ulm/

Primary Examiner, Art Unit 1649